June 12, 2023

Acting Deputy Associate Commissioner Travis Hall
National Telecommunications and Information Administration
US Department of Commerce
1401 Constitution Ave NW, Room 4725
Washington DC 20230

AI Accountability Policy for Request for Comment
Docket No. 230407-0093

Dear Commissioner Hall:

Johnson & Johnson ("J&J") appreciates the opportunity to submit input on the Artificial Intelligence (AI) Accountability Policy Request for Comment. We commend NTIA's engagement of the broader stakeholder community on important topics around the current state of play, including gaps and barriers to accountability for and trust in AI systems, and we share the goal of trustworthy, ethical and equitable application of AI.

J&J is the world's most comprehensive and broadly-based manufacturer of healthcare products. For nearly 130 years, we have led the way in innovation and are continuing this heritage today by bringing important new pharmaceutical products and medical technology innovations to market in a range of therapeutic areas on behalf of all our current and future patients. We understand that AI is – and will continue to be – a dynamic tool to improve healthcare, with the potential to help address some of the biggest challenges with more efficiency and better outcomes across the patient pathway. AI impacts the entire value chain from R&D and clinical trials to supply chain, speeding access to better and personalized treatments for patients. J&J is currently applying AI for the discovery of new drugs, the optimization and personalization of surgical instruments and implants, for example in creating algorithms to optimize the use of a device in surgery based on the tissue type, as well as in the identification of rare adverse events and pharmacovigilance.

Across our company, we approach AI in an ethical, compliant, and secure manner, and we understand that public trust is the cornerstone of unleashing the potential of AI and achieving a truly patient-centric experience across the healthcare ecosystem. Our teams are guided by Our Credo and Business Code of Conduct, an Ethical Code for the Conduct of Research and Development, and commitments to Diversity, Equity and Inclusion. Our bioethical principles include transparency, integrity, and respect for the rights and welfare of all persons and for championing ethical decision-making and policies.

**Enabling the Potential of AI Ethically**

In order to ensure a prosperous socioeconomic and environmental evolution based on AI, its development and use should respect ethical principles, particularly in health care where bioethics is foundational for practitioners, healthcare companies and authorities. However, to achieve ethical, trustworthy and sustainable AI, we need more than principles. We should also have an appropriate and agile policy framework that fosters innovation, builds a data culture that enables AI while respecting personal data privacy protection, supports social cohesion by educating people and upskilling the healthcare workforce, promotes ethical behavior uptake in industry and the public sector, and seeks international cooperation.

Application of ethical principles is required throughout the AI lifecycle, from development to deployment. AI is like any other new technology; its value for good or ill is in its application, not in

the technology itself. J&J supports the Business Roundtable AI Roadmap for Responsible AI[1] and their Recommendations for Responsible Artificial Intelligence,[2] including embedding AI rules and guidelines into existing frameworks, as appropriate; adopting regulatory approaches to AI that are contextual, proportional and use-case specific; and employing an adaptive approach to enforcement.

J&J is committed to ethics-based decision making as a central tenet in our processes. Some examples of our work deploying our ethical approach include our efforts in compassionate use through the CompAC[3] initiative which ensures fair, objective and ethical evaluations of patient requests for investigational medicine. In addition, we are a leader in initiatives to improve clinical trial data transparency, as evidenced by our commitment to data sharing through the Yale Open Data Access (YODA) Project,[4] a model that provides a fair and unbiased approach for assessing external requests for the use of clinical trial data.

**AI Accountability: AI Policies**

Any policy regarding AI should have a clear scope and framework, facilitating implementation and avoiding complexity, to build trust between citizens, developers, deployers and users and create a favorable environment that fosters innovation. Policy development should begin with an assessment of existing policies and regulations, including applicable sector-specific laws and guidelines, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Highly regulated sectors, like the healthcare industry, have existing frameworks for addressing relevant risks (e.g., safety, security, privacy), and these frameworks should be evaluated for their contribution and applicability to AI accountability. It is also imperative that policymakers consider the international implications of any requirements or regulation, from how they might impact innovation and a nation's competitive advantage to how they might foster harmonization and capacity building to provide greater, more equitable access safely for all.

We are committed to partnering with policymakers and stakeholders to define the foundations for the development, application, ethics and regulation of digital technologies, for which J&J proposes the following recommendations:

- **Policy approach:** We support development of a framework that is proportional, risk-based, predictable and innovation-friendly to encompass the evolution of AI technologies and their applications, and recognizes ethical risk might change drastically according to its use and context.
- **Data as a key enabler of AI:** We encourage authorities to collaborate with industry and civil society in building data ecosystems which help generate meaningful datasets in quantity and quality, ensuring and enabling a fair and ethical AI ecosystem that provides appropriate levels of data protection. Policies should appropriately value the opportunity to improve citizens' health and healthcare systems through the use of data-driven approaches. These approaches rely on the collection, analysis, and – importantly -- sharing of health data to better understand diseases and treat them as part of a system

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1 https://s3.amazonaws.com/brt.org/Business_Roundtable_Artificial_Intelligence_Roadmap_Jan2022_1.pdf

2 https://s3.amazonaws.com/brt.org/Business_Roundtable_Artificial_Intelligence_Policy_Recommendations_Jan2022_1.pdf

3 https://www.janssen.com/compassionate-use-pre-approval-access/compassionate-use-advisory-committee

4 https://yoda.yale.edu/johnson-johnson

delivering more personalized healthcare, which is increasingly more targeted, effective and efficient.

- **Social inclusion and cohesion:** Understanding and trust for AI should be facilitated by improved educational and professional training systems, for example enhancing digital skills in the healthcare workforce and general digital literacy, across geographies, to ensure cohesive and inclusive development and adoption of AI across the US.
- **Self-regulation:** We promote a 'holistic' approach, including high-level principles, best practices, voluntary and industry-driven standards (complementing but not replacing existing regulations). Industry should be encouraged to self regulate: companies should establish and implement guiding ethical and governance principles that apply throughout all their operations, as with the National Institute of Science and Technology Privacy[5] and Cybersecurity[6] Frameworks.
    - We support accountability models that incentivize the detection and remediation of errors, bias, and other risks ("find-and-fix") over approaches that penalize the discovery of such errors ("find-and-fine"), in the absence of significant wrongdoing.
    - The process or context in which AI is embedded must also be fair and ethical, which goes beyond the scope of the AI per se and is critical to evaluating the ultimate impact.
- **Privacy and Data Protection:** Clear and consistent standards of collection, storage, and processing of data will enable information to be shared, combined and used for the purposes of operating AI applications securely and respectfully to facilitate innovation. There are aspects of AI that are of relevance for privacy, including anonymity, confidentiality and control, which should guide choices for AI system design, development and deployment.
    - Some systems utilize personal data, while other systems use data that cannot be linked to individuals. There must be appropriate basis and safeguards for the use of personal data, including consent, as required. Additionally, use of personal data should be in line with the purpose for which it has been collected. Health care data is among the most sensitive of types of data and therefore needs adequate protection.
    - Further, we believe a comprehensive national framework can help ensure a more consumer- and patient-centric approach to managing personal information while ensuring consistent privacy protections, reducing variability across individual governments and government agencies, allowing a greater flow of data, and maintaining appropriate protections.
- **Addressing Bias:** We recognize the critical need to address the propensity of AI applications to express bias based on the data on which they are trained, especially in the health care space where disparities in health outcomes are a disappointingly persistent reality. Diversity, equity and inclusion must be considered in all aspects of AI (e.g., selecting the issues to address/problems to solve using AI, training and hiring a diverse workforce from the data scientists to programmers, attorneys, and program managers). Not all data is created equal, and data that is not reflective of the population it intends to help or the unbiased problem it intends to solve does not have the proper level of quality upon which society can rely. Fostering participation by diverse populations will help enable data generation that simultaneously improves the authenticity of data sets and the inclusivity of data-driven insights. AI systems must continually be

[5] https://www.nist.gov/privacy-framework/privacy-framework
[6] https://www.nist.gov/cyberframework

monitored, and models must be adjusted for fitness for purpose, accuracy and resilience, in addition to monitoring and testing datasets for accuracy and to avoid unfair bias.

- **Explainability:** Developing a framework to enhance the explicability of AI systems that support decision-making on socially significant issues, such as healthcare, is a component of building societal trust. It is important that the workings of the models can be explained to non-experts. Therefore, central to a supportable framework is the ability for individuals to obtain a factually correct, and generally clear explanation of the decision-making process, especially in the event of unwanted consequences. This is likely to require the development of frameworks specific to different industries.
- **International cooperation**: We support international cooperation on ethical guidelines to ensure an inclusive, consistent, and global approach. Goals for international policymaker cooperation include aligning on key definitions, promoting interoperability, addressing data localization requirements that impact cross border data flows and establishing means of collecting fully representative training data.
- **Increasing digital literacy and access:** Making investments in digital access and literacy is critical to ensure citizens and patients are empowered to manage their own data, understand the benefits of AI, and have the tools to make informed decisions with respect to the use of their data. Increased digital access and literacy can help the public understand the benefits of data and appropriate data sharing and the benefits of safety and ethical frameworks. In addition, these investments can help drive the development of a diverse workforce, which will be critical to overcome the "digital divide," stemming from socio-demographic disparities in the US, such as gender, race and ethnicity, age, and geography, and enabling populations who might benefit the most from data applications to be involved in, and have access to, these developments.

**Harnessing the Promise of AI**

At J&J, we recognize the power and promise of AI in healthcare. We take seriously our role as collaborator and innovator in healthcare, contributing new ideas, solutions, technology, partnerships, and perspectives on digital policy. We are focused on increasing engagement and collective action across stakeholders to connect patients, providers, and policymakers in understanding how harnessing the potential of AI in healthcare can help everyone, if we address barriers and support enablers through comprehensive federal approaches.

Please let us know if you may need additional information and we look forward to contributing to this ongoing dialogue and serving as a resource. If you have any questions, please e-mail Carla Cartwright at ccartwr@its.jnj.com.

Sincerely,

Andrea Masciale
Vice President, Global Policy